FEB 1 2 2002 K011835

510(k) Summary

SUBMITTER: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Lynne Leonard
Phone: (303) 467-6586
Fax: (303) 467-6429

DATE PREPARED: June 1, 2001

DEVICE TRADE NAME: COBE® Revolution™ Centrifugal Blood Pump

COMMON/USUAL NAME: Centrifugal Blood Pump

CLASSIFICATION NAME: Non-roller type cardiopulmonary bypass blood pump (21 CFR 870.4360)

PREDICATE DEVICE: Medtronic BP-80 BioPump® Centrifugal Blood Pump (K852698)

DEVICE DESCRIPTION:

The COBE® Revolution™ Centrifugal Blood Pump is an extracorporeal blood pump that utilizes a rotating vaned impeller design to move blood by centrifugal force. The device is provided sterile with a non-pyrogenic fluid pathway, and is for single use only. It is indicated for use with a Stöckert Instrumente GmbH Centrifugal Pump console in cardiopulmonary bypass procedures for periods of up to six hours. The device has not been qualified for longterm use (greater than six hours) as a bridge to transplant, for pending recovery of the natural heart or extracorporeal membrane oxygenation (ECMO).

The Revolution Pump consists of a rotating vaned impeller within a pump housing. The pump housing has two components, a top and bottom case, and features a central, single-barbed, 3/8" inlet port and tangential, double-barbed, 3/8" outlet port. The vaned impeller is molded onto a steel shaft that supports it at its axis of rotation, with the shaft rotating on a bearing at each end. The device contains a multi-pole magnet that is fully enclosed within the magnet housing and impeller, and thus does not contact the blood pathway. The magnet is designed to magnetically couple with the pump drive unit of the Stöckert Instrumente GmbH Centrifugal Pump console. Rotation of the magnet causes the impeller to rotate and pump blood via centrifugal force.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Revolution Pump is substantially equivalent to the currently marketed Medtronic BP-80 BioPump® Centrifugal Blood Pump (K852698) in intended use and operating principle.

Substantial Equivalence Table

Parameter	COBE Revolution Pump	Medtronic BP-80
Priming Volume	57 ml	80 ml
Maximum Blood Flow Rate	8 liters/minute	Not specified
Maximum Operating Pressure	800 mm Hg	900 mm Hg
Impeller Design	Rotating vaned impeller	Vaneless rotating cones
Bearing Design	No seals	Sealed bearings
Motor Interface	Magnetic coupling	Magnetic coupling
Inlet/Outlet Port Diameters	3/8 inch	3/8 inch
Sterilization Method	Ethylene Oxide	Gamma Radiation

In-vitro test data demonstrate that the COBE® Revolution™ Centrifugal Blood Pump is substantially equivalent to the Medtronic BP-80 BioPump® Centrifugal Blood Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Ms. Lynne Leonard
Sr. Regulatory Affairs Manager
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K011835
Trade Name: COBE Revolution Centrifugal Blood Pump
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass blood pump
Regulatory Class: Class II (two)
Product Code: KFM
Dated: February 4, 2002
Received: February 5, 2002

Dear Ms. Leonard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): K011835

Device Name: COBE® REVOLUTION™ Centrifugal Blood Pump

Indications For Use:

The COBE® REVOLUTION™ Centrifugal Blood Pump is intended to be used with a Stöckert Centrifugal Pump console in cardiopulmonary bypass procedures for periods of up to six hours.

The pump has not been qualified through in vitro, in vivo, or clinical studies for long term use (i.e., longer than six hours) as a bridge to transplant, for pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011835

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)